PHARMACY

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

What is acceptable practice for dating and using multidose vials?

An open multidose vial may be used up to the expiration date on the label as long as the product does not show any evidence of contamination such as particulate matter or discoloration, unless contraindicated or specified otherwise by the manufacturer. With the advice of the Quality Assurance Committee and medical director, the facility should establish a policy that will ensure a stable and non-infectious product such as dating the vial when initially opened.

REGULATORY FOCUS BULLETIN
FOR YOUR INFORMATION

FILE TOPIC: Pharmacy

NOTE: "FYI is an informational and educational service of the Regulatory Focus Committee to assist you in finding the resources for answers to questions regarding issues not regulated by the Division of Health Service Regulation.

Must insulin be refrigerated?

The temperature for storing insulin should not exceed 75 degrees Fahrenheit. Studies regarding the stability of insulin stored at room temperature provide various time frames, 30 days to 18 months, but none of the studies has been performed for temperatures greater than 75 degrees Fahrenheit. It is the facility's responsibility to develop a policy regarding the storage of insulin and follow the manufacturer's recommendations.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

How quickly should a consultant pharmacist submit his/her written report to the facility after monthly reviews?

Federal regulations require documentation of services and for written reports to be submitted to the physician and director of nursing.

Prompt action is necessary if the pharmacist observes a situation which may cause harm to a resident, e.g. adverse reaction to a drug or medication error. The facility and pharmacist do open up liability issues when findings relative to drug regimen reviews are not submitted and/or documented, as well as followed up, in a timely manner.

Licensure rule .2603(a) states that potential drug therapy irregularities or discrepancies must be reported monthly following the pharmacist's assessments.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

What are the limitations for borrowing drugs?

Licensure rule .2306(d)(3) prohibits the borrowing of drugs except in an emergency. An emergency in this instance is a matter of professional judgment. When medications are borrowed, there is to be proper documentation and prompt replacement in accordance with the facility's policies. The administrator, director of nursing, and pharmacist should be made aware of problems with medications not being available. The facility should assure policies and procedures regarding the ordering, delivery and the establishment of a reliable drug procurement system and that utilization of emergency drug kits are followed in order to prevent the need to borrow drugs.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

What is an acceptable "drug not available" policy?

Licensure rule .2601(b) states: "The facility shall be responsible for obtaining drugs, therapeutic nutrients and related products prescribed or ordered by a physician for residents in the facility. Resources such as hospitals, wholesalers, and other pharmacies in the community should be contacted to obtain drugs that are not available from the provider pharmacy. If the drug cannot be obtained within a reasonable time period, the physician should be notified."

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

May drugs be stored at bedside with a physician's order even if a patient is not capable of self administering a medication?

Yes, for staff convenience if the facility has policies for proper secure storage of drugs at the resident's bedside. These policies are to be implemented for the safety and welfare of all residents in the facility.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

What is an acceptable time frame for drugs being available after ordering?

The interpretive guidelines for Tag F425, 42 CFR §483.60 state: "The facility is responsible under 42 CFR §483.75(h) for the "timeliness of the services." A drug, whether prescribed on a routine, emergency, or as-needed basis, must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort or endangers his or her health and safety, then this requirement is not met."

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

What is an acceptable margin of error in pouring a dose of liquid medication?

Although there are drugs that would not be harmful if the exact dose was not administered, there are many potent drugs that require precise dosage evaluation. Therefore, there is no certain percentage of margin of error that can be accepted for all liquid medications due to the significance of error being based on the medication being poured.

Staff should utilize measuring devices that have increments for the amount to be poured. Depending on the medication, nursing or pharmacy personnel may contact physicians and request a change in the order to a dosage that is more practical to measure accurately.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

What constitutes a medication error? At what point should a medication error be written up as an incident?

Licensure rule .2306(d)(1) states: "All medications or drugs and treatments shall be administered and discontinued in accordance with signed medical orders which are recorded in the patient's medical record." Anytime a dose of medicine is given in a manner that deviates from the way the physician ordered it, the manufacturer's specifications regarding preparation and administration of the drug or from facility policy there is a medication error. A medication error has occurred if one or more of the following is not correct as specified in the order: the patient, the dose, the drug, the route, or the time of administration. Some documentation of a medication error should exist, and in certain situations, an adverse incident report should be filed. Every facility should establish a policy regarding medication errors, including what steps are to be taken to rectify the problem, if possible, and what sort of documentation is warranted.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

Should PRN medications be charted on both sides of the MAR?

Nurses are responsible for charting the medication and amount given, the reason and the effectiveness of a PRN medication. This information is to be documented in the medical record, such as on the back of the MAR or in the nurses' notes. Documentation should be consistent, and any medication administered is to be properly documented on the front of the MAR.

REGULATORY FOCUS BULLETIN
FOR YOUR INFORMATION

FILE TOPIC: Pharmacy

NOTE: "FYI is an informational and educational service of the Regulatory Focus Committee to assist you in finding the resources for answers to questions regarding issues not regulated by the Division of Health Service Regulation.

How long are stock drugs good after they are opened?

Expiration dates on labels are based on stability studies of the drug product in the original unopened container. Even so, drugs are considered to be in date until the manufacturer's expiration date has lapsed, assuming proper storage and packaging as recommended by the manufacturer. Exceptions apply to any drug that a manufacturer has identified as having a shortened expiration date once opened.

To ensure that a drug product meets standards of identity, quality and purity at the time of use, consultant pharmacists should develop, coordinate and supervise proper policies and procedures of individual facilities, including storage and labeling.

Routine medication not dispensed in their original containers should carry an appropriate expiration date as determined by the dispensing pharmacist.

REGULATORY FOCUS BULLETIN
FOR YOUR INFORMATION

FILE TOPIC: Pharmacy

NOTE: "FYI is an informational and educational service of the Regulatory Focus Committee to assist you in finding the resources for answers to questions regarding issues not regulated by the Division of Health Service Regulation.

What is the acceptable time period for expiration dates on medication labels that are not in the original manufacturer's packaging, but prepackaged by individual pharmacies in unit dose?

It should be emphasized that pharmacists have a professional responsibility to ensure the integrity of all drug products under their supervision.

The current edition of the US Pharmacopoeia (XII) states that a dispenser must take into account a number of factors in determining reduced expiration dating. Relevant factors include the nature of the drug, the container, and the storage conditions. Current USP policy states "Unless otherwise required, the dispenser may, on taking into account the foregoing, place on the label of a multiple-unit container a suitable beyond-use date to limit the patient's use of the drug. Unless otherwise specified in the individual monograph, such beyond use date shall be not later than (a) the expiration date on the manufacturer's container, or (b) one year from the date the drug is dispensed, whichever is earlier.

The USP also provides that for Single Unit Containers and Unit-Dose Containers for Non-sterile Solid and Liquid Dosage Forms, "In the absence of stability date to the contrary, such date should not exceed 1) 25% of the time remaining between the date of repackaging and the expiration date on the original manufacturer's bulk container, or 2) six months from the date the drug is repackaged, whichever is earlier.

According to available CMS interpretations, the information above is only a guideline for reduced expiration dating for drugs dispensable in multiple-dose containers. Since the language is permissive, the pharmacist is free to estimate a reduced expiration date based on the relevant factors listed above. CMS has also stated through a CMS 1988 memorandum that "bingo" cards (punch cards or "bubble packs") are considered to be unit dose packages. USP standards also consider this type of package to be "unit-dose."

References

1. US Pharmacopoeia, XXII, Rockville, MD, US Pharmacopeial Convention, 1990.
2. Feinberg, J.L. "Expiration date labeling...", Consult Pharm 1989, 438, 440.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

If a resident wishes to keep an over-the-counter medication at his/her bedside, does the interdisciplinary care planning team need to be aware of such a practice and does a notation need to be placed in the resident's care plan?

Yes. Over-the-counter medication may be kept at the bedside for self administration. Regulation 42 CFR §483.10(n) states that "an individual resident may self administer drugs if the interdisciplinary team, as defined by 42 CFR §483.20(d)(2)(ii) has determined that this practice is safe." The interpretive guidelines also address documentation in the care plan and the storage of these drugs for self administration.

State licensure regulations require drugs that residents wish to keep at the bedside be stored in a manner to prevent easy access by wandering, confused residents. This storage may include a closed cabinet, private bathroom, or closed drawer. A physician's order is required for residents to self-administer medications and the order should indicate that medications may be stored at the bedside. Facility policy dictates issues such as labeling.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

Is it a deficiency to leave expired drugs on the medication cart since the facility has thirty days to return expired drugs?

Expired medications are to be removed from areas storing in-date medications, prior to or at the time of expiration. The facility is to have a designated area for the storage of expired products until the products are disposed of in accordance with the facility's policy. Nurses should check the expiration dates of medications, especially ones not used routinely, prior to the administration or use. Inappropriate storage of expired drugs is regarded as a safety and environmental issue.

Regulation 10 NCAC 13D .2605(a)(4) regarding the removal of expired drugs by the pharmacist within 5 days after the expiration date to the removal of drugs from the facility, not the removal of expired medications from storage areas such as medicine carts or cabinets in medication rooms.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

Page Reserved

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

If a resident is sent to the hospital and admitted but the family holds the room -- are the drugs returned to the pharmacy or do they remain in the patient's medicine drawer on the medication cart? If medications are returned to the pharmacy, can the pharmacist send the same drugs back if the resident returns to the facility with the same medication orders?

Refer to Licensure regulation 10 NCAC 13D .2605(b). Drugs may be held for not more than 30 days after the date of discharge. The storage and disposition of residents' medications is to be in accordance with the facility's policy and procedures. Once the drugs are returned to the pharmacy, the pharmacist needs to use his/her professional and legal judgment regarding the disposition of the medications.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

Due to the conversion of dosage from grains to milligrams, could a facility be cited for giving 300 mg of ferrous sulfate rather than 325 mg although both are 5 grains?

No. Differences among companies exist for ferrous sulfate, ASA, ferrous glucomate and Tylenol. This can lead to confusion in dosage conversions. The facility should be aware of the strength that its pharmacy dispenses, and physician orders should be the same as what is dispensed.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

May drugs have automatic stop orders?

Automatic stop orders should be established for all drugs. The majority of drugs such as antihypertensives will have a stop order that coincides with the renewal of orders (e.g., 30 or 90 days). Other drugs such as antibiotics for acute episodes will have a shorter stop order (e.g., 10 days).

Automatic stop orders should specify the type of product. For example, if the facility's stop order for corticosteroids is 14 days, then all corticosteroid products should be included, unless otherwise stated in the facility's policy.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy

What is the acceptable length of time that medications can remain in the facility after a resident is discharged from the facility? (The resident has the intent to return back to the facility from the hospital.)

Thirty (30) days. Licensure rule 10 NCAC 13D .2605(b) states: "Upon discontinuation of a drug or upon discharge of a patient, the remainder of the drug supply shall be disposed of promptly. If it is reasonably expected that the patient shall return to the facility and the drug therapy will be resumed, the remaining drug supply may be held for not more than 30 calendar days after the date of discharge or discontinuation."

Note: Medicaid residents are allowed one dispensary fee per month.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy
DATE: March 1997

Many medications have recommendations to be administered with food to prevent GI related adverse effects (e.g., NSAIDs), and physician orders for these medications read "...with food." Would a package of graham crackers or a package of saltines meet the intent of the order and satisfy regulations for those drugs which require administration with food? (The physician is satisfied with graham crackers or saltines.)

A package of graham crackers contains three 2 1/2" x 2 1/2" crackers and a package of saltines contains two 2" x 2" crackers, and are acceptable amounts of food to be used when administering medications. Although there are no specific parameters given for the amounts of food to be taken with medications, a teaspoon of applesauce would not meet the intent "with food." Three to four ounces of semi-solid food is recommended. The "with food" is intended to prevent possible GI distress and/or aid in drug absorption. Therefore, mealtime would be an appropriate schedule unless otherwise ordered or contraindicated.

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy
DATE: September 2004

What are facility responsibilities in regard to residents receiving medications via the Internet, catalogs, or other mail-order vehicles?

The Social Security Act, sections 1819(b)(A)(4)(iii) and 1919(b)(4)(A)(iii), places the responsibility for accurately administering drugs on the facility. This gives the facility the right to define specific standards for labeling, packaging, storing, processing, and administering of drugs. These provisions of the act allow the facility to develop policies to ensure the standards are upheld. Therefore facility policies would determine permissible methods of obtaining medications and biologicals.

1919(b)

(4) PROVISION OF SERVICES AND ACTIVITIES.–

(A) IN GENERAL.–To the extent needed to fulfill all plans of care described in paragraph (2), a nursing facility must provide (or arrange for the provision of)…

(iii) pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident; …

1819(b)

(4) PROVISION OF SERVICES AND ACTIVITES.–

(A) IN GENERAL.—To the extent needed to fulfill all plans of care described in paragraph (2), a skilled nursing facility must provide, directly or under arrangements (or, with respect to dental services, under agreements) with others for the provision of— …;

(iii) pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident; …

REGULATORY FOCUS BULLETIN

FILE TOPIC: Pharmacy
DATE: August 2006

Must a facility allow a resident to use a pharmacy of choice (proprietary or Veteran's Administration etc.) to dispense prescribed drugs when the pharmacy procedures and practice routinely prevent timely or accurate procurement of the drugs thereby creating a failure to comply with the resident's medical plan of care?

No. The facility must explain to the resident the reasons the resident's choice of pharmacy cannot be utilized so not to be interpreted as a violation of the right to choose.